Individual Safety Report

3337879-0-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

McNeil Consumer Healthcare

McNeil Consumer Healthcare
Fort Washington, PA 19034-2299

Page ____ of ____

Approved by FDA on 11/15/93

Mfr report #

UF/Dist report #

FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
unknown In confidence	18 yrs or ____ Date of birth:	( )female (X)male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

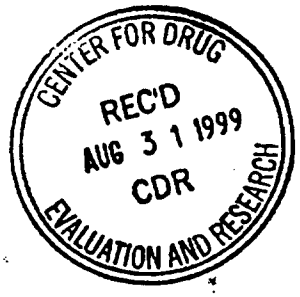
( ) death (mo/day/yr)
( ) life-threatening
(x) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
( ) other:

3. Date of event (mo/day/yr): unknown

4. Date of this report (mo/day/yr): 08/23/99

5. Describe event or problem

Pharmacist report of OVERDOSE (acetaminophen overdose) allegedly associated with an unknown acetaminophen product in an 18 year old male. According to pharmacist, patient was admitted to hospital for the treatment of acetaminophen overdose. Patient's liver enzymes were reportedly elevated (LIVER FUNCTION ABNORMAL) and approximately 20 hours post ingestion, patient's acetaminophen level was reportedly 131 mcg/ml. As of 8/23/99, patient was hospitalized and receiving unspecified treatment. No further information was provided.



6. Relevant tests/laboratory data, including dates

approximately 20 hrs post-ingestion: acetaminophen level= 131 mcg/ml; unspecified time: liver enzymes reportedly elevated

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

unknown

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 unknown acetaminophen product

#2

2. Dose, frequency & route used

#1 unknown dose, po

#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 unknown date

#2

4. Diagnosis for use (indication)

#1 unknown

#2

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)

#1 unknown

#2

7. Exp. date (if known)

#1 unknown

#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

unknown

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Healthcare
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-273-7820

3. Report source (check all that apply)

( ) foreign
( ) study
( ) literature
( ) consumer
(x) health professional
( ) user facility
( ) company representative
( ) distributor
( ) other:

4. Date received by manufacturer (mo/day/yr): 08/23/99

5. (A) NDA # 19-872
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
(X) Initial ( ) follow-up #

8. Adverse event term(s)

OVERDOSE LIVER FUNC ABNO

9. Mfr. report number

1227130A

E. Initial reporter

1. Name, address & phone #

Dr. [redacted]
[redacted] Medical Center, Dept. of Pharmacy
[redacted] Avenue
[redacted]

DSS

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
(X) Yes ( ) No	pharmacist	( ) Yes ( ) No (X) Unk

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.